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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,571	05/16/2005	James Langham Dale	23558-0017	4029

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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,571	DALE ET AL.	
	Examiner	Art Unit	
	CATHY K. WORLEY	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,70-77,81-89,91 and 93-138* is/are pending in the application.

4a) Of the above claim(s) *81-86 and 109-138* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,70-77,87-89,91 and 93-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/05; 12/28/05; 12/06/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received on Jan. 25, 2008 from John P. Isacson, the election with traverse of group III, claims 1, 70-77, 87-89, 93-108, 78-80 (in part) and 90-92 (in part) as they relate to SEQ ID NOs:6, 7, and 8, is acknowledged. The Applicant has pointed out that SEQ ID NO:s 6 and 7 comprise SEQ ID NO:8 (see page 13 of the response filed on Jan. 25, 2008); therefore, these should be rejoined. Accordingly, the Examiner is rejoining groups I, II, and III. In the response filed on May 20, 2008, the Applicant has clarified that claims 78-80 are cancelled, and therefore, they are not examined in this Office Action.

Claims 1, 70-77, 81-89, 91, and 93-138 are pending in the instant application. Claims 81-86 and 109-138 are withdrawn because they are directed to non-elected inventions. Claims 1, 70-77, 87-89, 91, and 93-108 are examined in this Office Action. This restriction requirement is **MADE FINAL.**

Specification

2. The abstract is objected to because there were two abstracts submitted on Jan. 18, 2005; one is the abstract on the front page of WO 2004/007729,

and the other is an abstract submitted on a separate page, numbered -3- and having attorney docket No.: 21415-0013 on the top right corner. These two abstracts are different, and therefore, the Applicant should submit one abstract with a statement that it takes the place of the abstracts submitted on Jan. 18, 2005. The new abstract should specify the virus from which the elected sequence was taken.

3. The specification is objected to because there are large blank areas. Pages 3 and 8 have large blank areas. The Applicant is advised to amend the specification to delete these large blank areas.

4. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed. The new title should specify that the promoter is taken from the Taro bacilliform badnavirus.

Claim Objections

5. Claims 73-77, 99, and 102-108 are objected to.

Claims 73-76 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the

claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 73-76 recite limitations that appear to be inherent properties of the promoter of the instant invention. The taro badnavirus promoter inherently initiates transcription constitutively in all of the plants recited in these claims; therefore, these claims do not further limit the DNA molecule that is being claimed. If the Applicant intended to claim a plant that has been transformed with the DNA molecule, then these claims need to be re-written such that the subject of the claim is the plant rather than the DNA molecule.

Claims 73-76 are also objected to because they are scientifically incorrect. The promoter of the instant invention is not expressed, but it initiates transcription of a downstream sequence thereby causing the downstream sequence to be expressed. One way to state this that would be technically correct would be "wherein an operably-linked nucleic acid sequence is expressed constitutively". However, this is an inherent function of the DNA molecule, therefore, it would not properly further limit the parent claim.

Claim 77 is objected to because of the following informalities: the article "the" appears twice between "wherein" and "nucleotide". The Applicant is advised to delete one of the recitations of "the". Appropriate correction is requested.

Claim 99 is objected to because it is scientifically incorrect. A construct can encode a targeting sequence, however, a construct can not comprise a targeting sequence, because the targeting sequence is a protein, it is not DNA.

Claims 102-108 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 102-108 recite limitations that appear to be inherent properties of the construct of claim 87; therefore, these claims do not further limit the construct that is being claimed. If the Applicant intended to claim a host cell or a plant that has been transformed with the construct, then these claims need to be re-written such that the subject of the claim is the plant or host cell rather than the construct.

Claim 102 is also objected to because it is scientifically incorrect. The promoter of the instant invention is not expressed, but it initiates transcription of a downstream sequence thereby causing the downstream sequence to be expressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

> enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 70-77, 87-89, 91, and 93-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in these rejections.

The term "at least high stringency conditions" in claims 1 and 70 is a relative term which renders the claims indefinite. The term "at least high stringency conditions" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For the purpose of examination, this recitation will be interpreted as encompassing any hybridization conditions. This interpretation does not relieve the Applicant of responding to this rejection under 35 USC 112, 2nd paragraph.

Claims 71-74, 77, 87, 89, and 91 recite the limitation "the nucleotide sequence". There is insufficient antecedent basis for this limitation in the claims. Each of these claims refers back to a previous claim in which there are more than one nucleotide sequences recited (for example, claim 1 has a nucleotide sequence in lines 3-4, and in part a), and also in part b)). It is

unclear which nucleotide sequence in the parent claim provides the antecedent basis for "the nucleotide sequence" recited in claims 71-74, 77, 87, 89, and 91. For the purpose of examination, the Examiner will interpret this recitation to be referring to part "b)", and therefore the claims are inclusive of DNA molecules that hybridize to SEQ ID NO: 6 or 7. This interpretation does not relieve the Applicant of responding to this rejection under 35 USC 112, 2nd paragraph.

Claims 71 and 72 are indefinite because it is unclear what is meant by "obtained from". Does this mean that the sequence is unaltered from an endogenous wild-type viral sequence? Does this mean that the sequence is cloned into a viral vector? Does this mean that the sequence is derived from a viral sequence but has been altered in some way?

Claims 87-89, 93, and 94 are indefinite. Claims 87 and 89 recite "operably linked to a foreign or endogenous DNA sequence to be transcribed" which is indefinite. It is unclear what would make a DNA sequence "foreign" or "endogenous". Foreign to what? Endogenous to what? It is also unclear how a chimeric DNA construct can be "endogenous" to any organism. Claim 88 also recites "operably linked to the foreign or endogenous DNA sequence", therefore, it is also indefinite. Claims 93 and 94 each recite "the foreign or endogenous DNA sequence", and therefore, they are also indefinite.

Claim 95 recites "aimed at downregulating", and it is unclear what is meant by "aimed at".

Claim 96 recites "a transcribed region that represents a molecule", and it is unclear what is meant by "represents".

7. Claims 73-76, 87-89, 91, and 93-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NOs:6, 7, or 8 or that hybridizes to SEQ ID NO:6, 7, or 8 that is constitutively expressed in a monocotyledonous plant; and to a construct comprising said molecule operably linked to a sequence to be transcribed.

The Applicants describe the nucleic acid of SEQ ID NO:6 which is 1190 bases in length (see sequence listing), and they describe this as a constitutive promoter sequence (see page 26, lines 25-30). They describe this as a TaBV (Taro badnavirus) promoter (see page 55). The Examiner is assuming that clones with the designation Tas-1/TR comprise SEQ ID NO:6 (see Table 1 on page 50). This assumption is based on the fact that Tas-1/TR has 1190 bp. The Examiner is also assuming that clones designated as T600 comprise SEQ

ID NO:7 (which is 598 bases in length) and clones designated as T500 comprise SEQ ID NO:8 (which is 529 bases in length).

The Examiner requests confirmation that these assumptions are correct in the next communication to the Office in order to have a clear record.

Among the nucleic acids of SEQ ID NOs: 6, 7, and 8; SEQ ID NO:8 is the smallest fragment at 529 bases in length. The Applicants describe plasmids comprising constructs with GUS or GFP operably linked to these promoters (see pages 51-52). They describe plants transformed with these constructs as well as transient assays in transfected taro leaves (see pages 53-56). They describe the expression levels for constructs comprising T600 (SEQ ID NO:7) as higher than expression levels for constructs comprising T500 (SEQ ID NO:8) in banana; but the reverse was true in tobacco (expression for constructs comprising SEQ ID NO:8 was higher than for constructs comprising SEQ ID NO:7) – see page 57.

The Applicants do not describe any active promoters that do not comprise SEQ ID NO:8. The only DNA molecules that hybridize to SEQ ID NO:6, 7, or 8 or have 90% identity to SEQ ID NO:6, 7, or 8 that are described as having promoter activity; are DNA molecules that comprise SEQ ID NO:8; such as SEQ ID NO:7 which comprises SEQ ID NO:8.

The essential feature of the DNA molecule of this invention is that it is an active promoter that can initiate transcription in a plant (see claim 73

which recites "expressed constitutively" and claim 87 where the promoter is "operably linked to a foreign or endogenous DNA sequence to be transcribed").

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of DNA molecules that hybridize to SEQ ID NOs:6, 7, or 8 or have 90% identity to SEQ ID NOs:6, 7, or 8, that have promoter activity. The Applicants only describe promoters that comprise SEQ ID NO:8. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of DNA molecules that are effective for transcription in a plant. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the promoter activity of initiating transcription in a plant, it remains unclear what features identify DNA molecules capable of such activity. Since the genus of DNA molecules has not been described by

specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Nucleic acids that have 90% identity with SEQ ID NO:6 can have as many as 119 nucleotide substitutions relative to SEQ ID NO:6. Therefore this encompasses 4^{119} molecules. Nucleic acids that have 90% identity with SEQ ID NO:7 can have as many as 59 substitutions and nucleic acids that have 90% identity with SEQ ID NO:8 can have as many as 52 substitutions. Nucleic acids that hybridize to anyone of these sequences can have numerous mismatches, insertions, and/or deletions relative to SEQ ID NO: 6, 7, or 8. Therefore, this recitation encompasses an infinite number of molecules, many of which would not have promoter activity in a plant cell, and most of which were not in the possession of the Applicant at the time of filing. The Applicants have reduced to practice several molecules in experiments that demonstrate promoter activity in plant cells; all of which comprise SEQ ID NO:8. The Applicants have not reduced to practice any molecules that do not comprise SEQ ID NO:8 that have promoter activity. Accordingly, the specification fails to provide an adequate written description to support the genus of DNA molecules that have 90% identity to SEQ ID NO:6, 7, or 8 or that hybridize to SEQ ID NO:6, 7, or 8 and that cause constitutive expression or initiate transcription as set forth in the claims. (See Written Description guidelines published in 2008 online at http://www.uspto.gov/web/menu/written.pdf).

8. Claims 1, 70-77, 87-89, 91, and 93-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule comprising SEQ ID NO:8; and for a chimeric construct comprising said molecule, does not reasonably provide enablement for to a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NO:8 or that hybridizes to SEQ ID NO:8; or for a chimeric construct comprising said molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NO:6, 7, or 8 or

that hybridizes to SEQ ID NO:6, 7, or 8; and to a construct comprising said molecule. It is noted that claims 1 and 70-72 do not specify a function for the DNA molecule, therefore, these claims are inclusive of DNA molecules of unknown function.

The Applicants teach the nucleic acid of SEQ ID NO:6 which is 1190 bases in length (see sequence listing), and they teach that this as a constitutive promoter sequence (see page 26, lines 25-30). The Examiner is assuming that clones with the designation Tas-1/TR comprise SEQ ID NO:6 (see Table 1 on page 50). This assumption is based on the fact that Tas-1/TR has 1190 bp. The Examiner is also assuming that clones designated as T600 comprise SEQ ID NO:7 (which is 598 bases in length) and clones designated as T500 comprise SEQ ID NO:8 (which is 529 bases in length). Among the nucleic acids of SEQ ID NOs: 6, 7, and 8; SEQ ID NO:8 is the smallest fragment at 529 bases in length. The Applicants teach plasmids comprising constructs with GUS or GFP operably linked to these promoters (see pages 51-52). They teach plants transformed with these constructs as well as transient assays in transfected taro leaves (see pages 53-56). They teach that the expression levels for constructs comprising T600 (SEQ ID NO:7) were higher than expression levels for constructs comprising T500 (SEQ ID NO:8) in banana; but the reverse was true in tobacco (expression for constructs comprising SEQ ID NO:8 was higher than for constructs comprising SEQ ID NO:7) – see page 57.

The Applicants do not teach any active promoters that do not comprise SEQ ID NO:8. The only DNA molecules that hybridize to SEQ ID NO:8 or have 90% identity to SEQ ID NO:8 that are taught to have promoter activity; are DNA molecules that comprise SEQ ID NO:8. The Applicants do not teach any use for these DNA molecules other than to be used as promoters. Therefore, any DNA molecules that have 90% identity to SEQ ID NO:6, 7, or 8 or that hybridize to SEQ ID NO:6, 7, or 8 that are not effective as promoters in plants are not enabled by the instant specification.

There is a high degree of unpredictability in altering promoter sequences, and these claims are inclusive of sequences with insertions, deletions, and substitutions relative to the nucleic acid that has been shown to have promoter activity. For example, the state-of-the-art is such that one of skill in the art cannot predict which substitutions, deletions, or insertions can be made in a promoter sequence without altering or eliminating the promoter activity.

Mutation of promoter sequences also produces unpredictable results. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very

small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make multitudes of DNA molecules with substitutions, additions, and deletions relative to SEQ ID NO: 6, 7, or 8, and test each one for promoter activity in plant cells.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 70-77, 87-89, 91, and 93-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk et al (WO 99/00492; published on Jan. 7, 1999).

The claims are directed to an isolated DNA molecule that hybridizes to SEQ ID NO: 6, 7, or 8; including wherein the sequence is obtained from a virus or a badnavirus, and including wherein the sequence is expressed in specified plants; and to constructs comprising said DNA operably linked to a sequence to be transcribed, including wherein said sequence encodes a protein or a transcript capable of modulating expression of a corresponding target gene.

Schenk et al teach a promoter from the banana streak badnavirus (see entire document), and they teach DNA that hybridizes to this promoter (see page 2, line 31). This promoter has a region of high homology with the instant SEQ ID NO:8 (see alignment, attached at the end of this Office Action), and it inherently has the property of being capable of hybridizing to SEQ ID NO:8. Because the "at least high stringency conditions" have not been defined, the promoter taught by Schenk et al would also hybridize to

SEQ ID NOs: 6 and 7 under some stringency conditions, because it is an inherent property of DNA to hybridize to other DNA.

Schenk et al teach this promoter operatively linked to a coding sequence (see page 2, line 35). They teach plant cells and tissues comprising DNA constructs made with this promoter (see page 3). They teach transgenic banana plants (*Musaceae*) transformed with constructs comprising this promoter operatively linked to GUS and GFP (which is a screenable marker) with a nos 3' untranslated sequence (see figure 15 and figures 1-5), and they teach that constitutive-type expression was observed (see page 21, line 2). They claim a DNA construct having the promoter operatively linked to a sequence encoding an RNA or a polypeptide (see claim 7). They teach that the promoter can be utilized with an enhancer or silencer (see page 6, line 15). They teach that the promoter can be operatively linked to antisense RNA, a ribozyme, or a coding sequence that is translated into a polypeptide which functions as an enzyme, a structural component or has some other physiological effect (see page 6, lines 16-19). They teach an ER-targeted version of the GFP reporter gene which has an amino acid sequence targeting the polypeptide to an intracellular compartment (the ER) (see page 12, lines 4-9). They teach expression in both monocot and dicot cells (see page 12, lines 30-33). They teach the use of a selectable marker gene for use with kanamcyin selection (see page 15, last line). They teach a construct utilizing the intron-containing leader of the maize shrunken-1 gene (see page 16, line

18), and this is known to increase expression levels presumably by modulating the mRNA stability.

With regard to claim 76, specifically, the USPTO does not have laboratory facilities in which testing for expression in taro plants can be performed, however, due to the data presented by Schenk et al showing expression in several other monocot species, the DNA taught by Schenk et al is likely to have the inherent property of initiating transcription in taro plants. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would not the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

10. Claims 1, 70-77, 87-89, 91, and 93-108 are rejected under 35 U.S.C. 102(a) and 35 USC 102 (e) as being anticipated by Schenk et al (US Patent No. 6,391,639; issued on May 21, 2002, and filed on April 17, 2000 as a National Stage Entry of PCT/AU98/00493 which was published as WO 99/00492 on Jan. 7, 1999).

The claims are directed to an isolated DNA molecule that hybridizes to SEQ ID NO: 6, 7, or 8; including wherein the sequence is obtained from a virus or a badnavirus, and including wherein the sequence is expressed in specified plants; and to constructs comprising said DNA operably linked to a sequence to be transcribed, including wherein said sequence encodes a

protein or a transcript capable of modulating expression of a corresponding target gene.

Schenk et al teach a promoter from the banana streak badnavirus (see entire document), and they teach DNA that hybridizes to this promoter (see column 2, line 49). This promoter has a region of high homology with the instant SEQ ID NO:8 (see alignment, attached at the end of this Office Action – the sequences in US Patent 6,391,639 are identical to the sequences disclosed in WO 99/00492), and it inherently has the property of being capable of hybridizing to SEQ ID NO:8. Because the "at least high stringency conditions" have not been defined, the promoter taught by Schenk et al would also hybridize to SEQ ID NOs: 6 and 7 under some stringency conditions, because it is an inherent property of DNA to hybridize to other DNA.

Schenk et al teach this promoter operatively linked to a coding sequence (see column 2, lines 59-60). They teach plant cells and tissues comprising DNA constructs made with this promoter (see column 3). They teach transgenic banana plants (*Musaceae*) transformed with constructs comprising this promoter operatively linked to GUS and GFP (which is a screenable marker) with a nos 3' untranslated sequence (see figure 15 and figures 1-5), and they teach that constitutive-type expression was observed (see column 17, line 65). They claim a DNA construct having the promoter operatively linked to a sequence encoding an RNA or a polypeptide (see claim 5). They teach that the promoter can be utilized with an enhancer or silencer

(see column 5, lines 37-38). They teach that the promoter can be operatively linked to antisense RNA, a ribozyme, or a coding sequence that is translated into a polypeptide which functions as an enzyme, a structural component or has some other physiological effect (see column 5, lines 40-45). They teach an ER-targeted version of the GFP reporter gene which has an amino acid sequence targeting the polypeptide to an intracellular compartment (the ER) (see column 10, lines 25-32). They teach expression in both monocot and dicot cells (see Example 3, bridging columns 10 - 11). They teach the use of a selectable marker gene for use with kanamcyin selection (see column 13, line 42)). They teach a construct utilizing the intron-containing leader of the maize shrunken-1 gene (see column 14, lines 3-5), and this is known to increase expression levels presumably by modulating the mRNA stability.

With regard to claim 76, specifically, the USPTO does not have laboratory facilities in which testing for expression in taro plants can be performed, however, due to the data presented by Schenk et al showing expression in several other monocot species, the DNA taught by Schenk et al is likely to have the inherent property of initiating transcription in taro plants. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would not the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Patent Examiner, Art Unit 1638

ALIGNMENT

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<!--StartFragment-->RESULT 7
AAX06864
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XX
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FT /note= "this region is specifically claimed in Claim 2"
FT protein_bind 997. .1006
FT /*tag= d
FT /label= GATA-1
FT /note= "GATA binding factor 1 binding site"
FT protein_bind 1073. .1086
FT /*tag= e
FT /label= ATF
FT /note= "activation transcription factor binding site"
FT TATA_signal 1135. .1149
FT /*tag= f
FT prim_transcript 1173. .1181
FT /*tag= g
FT /note= "transcription initiation site"
FT promoter 1923. .1322
FT /*tag= c
FT /note= "this region is specifically claimed in Claim 3"
XX
PN WO9900492-A1.
XX
PD 07-JAN-1999.
XX
PF 26-JUN-1998; 98WO-AU000493.
XX
PR 26-JUN-1997; 97AU-00007593.
XX
PA (CSIR ) COMMONWEALTH SCI & IND RES ORG.
PA (QUEE-) STATE QUEENSLAND DEPT PRIMARY IND.
PA (UYQU ) UNIV QUEENSLAND.
PA (SUGA-) BUREAU SUGAR EXPERIMENT STATIONS.
PA (UYQU-) UNIV QUEENSLAND TECHNOLOGY.
PA (UYLE-) UNIV KATHOLIEKE LEUVEN.
XX
PI Schenk PMP, Sagi L, Remy S, Swennen RL, Dietzgen RG, Geering ADW;
PI Mcmichael LA, Thomas JE, Grof CPL, Elliott AR;
XX
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DR WPI; 1999-095738/08.
XX
PT New promoter that is operable in a plant cell - useful in genetic
PT engineering for regulation of gene expression.
XX
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PS Claim 1; Page 26; 52pp; English.
XX
CC This is the nucleotide sequence of the badnavirus promoter pCv that can
CC be used to confer high-level gene expression on transgenic plants. The
CC promoter was identified in viral DNA isolated from badnavirus-infected
CC leaf material of Australian banana cv. Williams (Musa group AAA).
CC Promoter DNA was obtained from viral DNA by PCR using degenerate primers
CC badnaT and badna3 (see AAX06867-68). Putative promoter elements were
CC identified using a computer program and by comparison with putative
CC promoter elements of other plant virus genome promoters. Claimed
CC promoters (see also AAX06863 and AAX06865) are useful for expressing a
CC gene product in a plant cell, including a monocot such as sugarcane,
CC banana, maize, millet or sorghum, a dicot such as tobacco, canola, Tipu
CC tree or Nicotiana benthamiana, a gymnosperm such as radiata pine, or a
CC fern (all claimed). The gene products can confer e.g. disease
resistance,
CC herbicide resistance, improved tolerance to environmental factors, or
can
CC modulate plant composition, development, and fruit or crop quality
XX
SQ Sequence 1322 BP; 441 A; 239 C; 335 G; 307 T; 0 U; 0 Other;
Query Match 6.3%; Score 74.4; DB 2; Length 1322;
Best Local Similarity 75.0%; Pred. No. 1.4e-10;
Matches 93; Conservative 0; Mismatches 31; Indels 0; Gaps 0;
Qy 2 CCTTCACGGGTTAGATGGTTGAAGTTCATTGATTATATTACTAACACTGGAATTGATGTT 61
|| ||| |||| |||||||| |||| ||| ||||| ||| || ||| | |||||
Db 271 CCCTCAAGGGTAAGATGGTTAGCTTTCACTGACTATATCACTGGAACAGGATTGGATGTG 330
Qy 62 AAATTTGAACATATTGATGCTAAAAATAATGTCTTAGCTGACACTCTGTCCAGGTTAGTT 121
|| ||||| |||||||| | || ||||||| |||| |||||||||| ||| ||||
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Qy 122 AACA 125
|| |
Db 391 AAAA 394
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/Cathy K. Worley/
Patent Examiner, Art Unit 1638